

**REMARKS**

Reconsideration of the rejection is respectfully requested in view of the above amendments and the following remarks.

***Claim Amendments***

Compound, composition and process for preparing claims 1-3, 6 and 9-10, have been amended so that all compound, composition and process for preparing claims pending in this application recite (either directly or through their dependency) the specific ester groups from page 23 of the specification, as suggested by the Examiner. Inasmuch as these amendments address the sole outstanding ground for rejection of these claims and should place these claims in condition for allowance, entry of these amendments after Final Rejection is believed to be appropriate and is respectfully requested.

Method claims 12 through 17 have been cancelled.

Method claim 19, which is directed toward the treatment of rheumatoid arthritis, has been amended to change its dependency from cancelled claim 17 to be dependent on compound claim 1, thus incorporating the specific ester groups from page 23 of the specification, as suggested by the Examiner. Inasmuch as this amendment addresses the sole outstanding ground for rejection of claim 19 and should place this claim in condition for allowance, entry of this amendment after Final Rejection is believed to be appropriate and is respectfully requested.

These amendments are being made to expedite the prosecution of this application, and without waiver or prejudice to Applicants' right to prosecute any subject matter thereby deleted in one or more continuing applications.

New method claim 20 is identical to claim 19, except that it is directed toward the treatment of psoriasis. Inasmuch as the Examiner has specifically acknowledged that the specification is enabling for treating rheumatoid arthritis and psoriasis, and this claim is otherwise of the same form and content as claim 19, claim 20 should also be in condition for allowance, and entry of this claim after Final Rejection is believed to be appropriate and is respectfully requested.

### ***Status of the Claims***

Following entry of the above amendments, claims 1-3, 5, 6, 8-10, 18 and 19 remain pending in this application.

### ***Claim Rejections – 35 U.S.C. § 112 ¶ 2 – Ester Issue***

Claims 1-3, 5, 6, 9, 10, 12 and 13 have continued to be rejected under 35 U.S.C. § 112, second paragraph, as being indefinite by reason of the phrase “*in vivo* cleavable ester.” (Action, paragraph 2, pages 2-3). Applicants remain of the position that a person skilled in this art would readily know, or know how to determine, what esters are encompassed by this phrase. Nevertheless, in order to expedite the prosecution of this application, all pending claims now incorporate (either directly or through their dependency) the specific ester groups from page 23 of the specification, as suggested by the Examiner, and claims 12 and 13 have been cancelled. Therefore this ground for rejection has been overcome.

***Claim Rejections – 35 U.S.C. § 112 ¶ 1 – Ester Issue***

Claims 1-3, 5, 6, 9, 10, 12 and 13 have continued to be rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification. (Action, paragraph 3, pages 3-7). Although the Examiner acknowledged that the specification is enabling for making the *in vivo* cleavable esters listed on page 23 of the specification, it is asserted that the specification does not reasonably provide enablement for making all *in vivo* cleavable ester. Applicants remain of the position that a person skilled in the pharmaceutical arts would readily know from their own knowledge, or be able to determine without undue experimentation and/or from the available literature at the time this application was filed (including the references specifically cited at specification pages 22-23), how to identify and make an appropriate scope of “*in vivo* cleavable esters.” Applicants and the undersigned take exception, *inter alia*, to the Examiner’s characterization of the application’s disclosure and guidance, as well as the level of skill and knowledge in the art with respect to such esters at the time this application was filed. Nevertheless, in order to expedite the prosecution of this application, all pending claims now incorporate (either directly or through their dependency) the specific ester groups from page 23 of the specification, as suggested by the Examiner, and claims 12 and 13 have been cancelled, but without prejudice to Applicants’ right to pursue the deleted subject matter in a continuing application. Therefore this ground for rejection also has been overcome.

***Claim Rejections – 35 U.S.C. § 112 ¶ 1 & 2 – “Disease Treatment Issue”***

Claims 12-18 continue to be rejected or are newly rejected in paragraphs 4, 5, 6 and 7 of the Action (extending from pages 7 to 24) as being indefinite and or not sufficiently enabled by the specification.

- In paragraph 4, claims 12, 14 and 15 are rejected as being indefinite with respect to the term “a disease or medical condition mediated by TNF.” In an effort to expedite the prosecution of this application to allowance, claims 12, 14 and 15 have been cancelled, without prejudice to Applicants’ right to prosecute the cancelled subject matter in a continuing application. This ground for rejection is therefore moot, and need not be considered further herein.
- In paragraph 5, claim 13 remains rejected as being indefinite with respect to the term “a disease or medical condition mediated by IL-1, IL-6 or IL-8.” In an effort to expedite the prosecution of this application to allowance, claim 13 has been cancelled, without prejudice to Applicants’ right to prosecute the cancelled subject matter in a continuing application. This ground for rejection is therefore moot, and need not be considered further herein.
- In paragraph 6, claims 12 and 13 remain rejected, and claims 14, 15 and 16 are newly rejected, on the ground that the specification “does not reasonably provide enablement for treating all TNF, IL-1, IL-6, or IL-8 mediated diseases.” In an effort to expedite the prosecution of this application to allowance, claims 12 through 16 have been cancelled, without prejudice to Applicants’ right to prosecute the cancelled subject matter in a continuing

application. This ground for rejection is therefore moot, and need not be considered further herein.

- In paragraph 7, claims 17 and 18 are newly rejected on grounds that the specification, “while being enabling for treating rheumatoid arthritis and psoriasis, does not reasonably provide enablement for treating all inflammatory disease.” While applicants take issue with some of the assertions made to support this rejection at pages 12 to 24 of the Action, and do not agree that the Examiner’s conclusion and ultimate rejection of these claims are supported by the case law, Applicants have cancelled claims 17 and 18 (without prejudice) in order to expedite this application to allowance. This ground for rejection is therefore moot, and will not be considered further herein.

All ground for rejection, therefore, have been addressed by amendment, or mooted by cancellation of the affected claims. Accordingly, all claims are now believed to be in condition for allowance.

### ***Conclusion***

The claim amendments have been made pursuant to the Examiner’s comments and suggestions as stated in the Final Rejection, and are believed to be consistent therewith. Moreover, it is believed that the amendments place this application in condition for allowance (or at least in better position for appeal). In particular, it should be apparent from the amendments and the above Remarks that the amendments do not require a further search, and do not require more than a minimal further effort by the

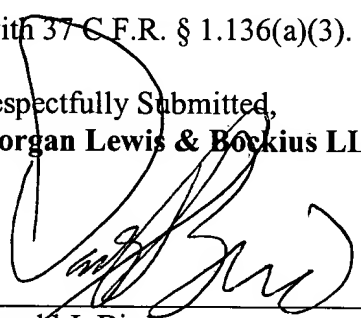
Examiner. Entry of these amendments after Final is, therefore, believed to be appropriate. Inasmuch as all amended claims are all believed to be condition for allowance, entry of the amendments and the allowance of all claims are respectfully requested.

**EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully Submitted,  
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